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DOCKET NO.: C1040.70012US00

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

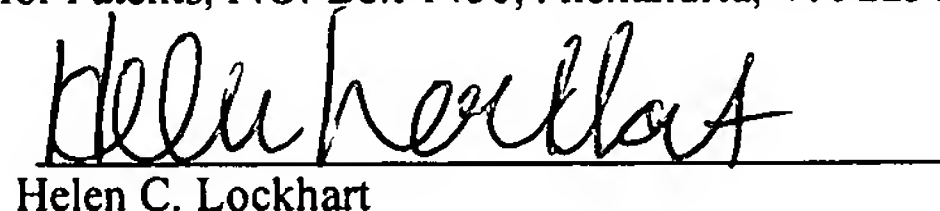
Applicant: Davis et al.  
Serial No.: 10/644,267  
Confirmation No.: 6263  
Filed: August 20, 2003  
For: NUCLEOTIDE VECTOR, COMPOSITION CONTAINING SUCH VECTOR  
AND VACCINE FOR IMMUNIZATION AGAINST HEPATITIS

Examiner: Not Yet Assigned  
Art Unit: 1632

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**CERTIFICATE OF MAILING UNDER 37 C.F.R. §1.8(a)**

The undersigned hereby certifies that this document is being placed in the United States mail with first-class postage attached, addressed to MAIL STOP AMENDMENT, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450, on the 3 day of December, 2004.

  
Helen C. Lockhart

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**MAIL STOP AMENDMENT**

Commissioner For Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Sir:

Transmitted herewith are the following documents:


- Information Disclosure Statement
- PTO Form 1449 with cited references
- Return Receipt Postcard

If the enclosed papers are considered incomplete, the Mail Room and/or the Application Branch is respectfully requested to contact the undersigned at (617) 646-8000, Boston, Massachusetts.

A check is not enclosed. If a fee is required, the Commissioner is hereby authorized to charge Deposit Account No. 23/2825. A duplicate of this sheet is enclosed.

Respectfully submitted,  
*Davis et al., Applicant*

By:

  
Helen C. Lockhart, Ph.D., Reg. No.: 39,248  
Wolf, Greenfield & Sacks, P.C.  
600 Atlantic Avenue  
Boston, Massachusetts 02210-2206  
Telephone: (617) 646-8000

Docket No.: C1040.70012US00  
Date: December 3, 2004  
xNDDx

DEC 06 2004

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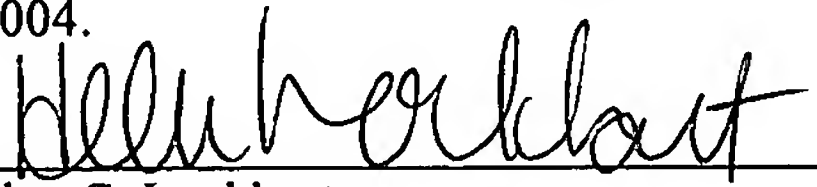
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AGAINST HEPATITIS

Examiner: Not Yet Assigned  
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Helen C. Lockhart

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**MAIL STOP AMENDMENT**

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

STATEMENT FILED PURSUANT TO THE DUTY OF  
DISCLOSURE UNDER 37 CFR §§1.56, 1.97 AND 1.98

Sir:

Pursuant to the duty of disclosure under 37 C.F.R. §§1.56, 1.97 and 1.98, the Applicant requests consideration of this Information Disclosure Statement.

PART I: Compliance with 37 C.F.R. §1.97

This Information Disclosure Statement has been filed before the mailing date of a first Office Action on the merits in the above-identified case.

No fee or certification is required.

PART II: Information Cited

The Applicant hereby makes of record in the above-identified application the information listed on the attached form PTO-1449 (modified). The order of presentation of the references should not be construed as an indication of the importance of the references.

The Applicant hereby makes the following additional information of record in the above-identified application.

PART III: Remarks

Documents cited anywhere in the Information Disclosure Statement are enclosed unless otherwise indicated. It is respectfully requested that:

1. The Examiner consider completely the cited information, along with any other information, in reaching a determination concerning the patentability of the present claims;
2. The enclosed form PTO-1449 be signed by the Examiner to evidence that the cited information has been fully considered by the Patent and Trademark Office during the examination of this application;
3. The citations for the information be printed on any patent which issues from this application.

By submitting this Information Disclosure Statement, the Applicant makes no representation that a search has been performed, of the extent of any search performed, or that more relevant information does not exist.

By submitting this Information Disclosure Statement, the Applicant makes no representation that the information cited in the Statement is, or is considered to be, material to patentability as defined in 37 C.F.R. §1.56(b).

By submitting this Information Disclosure Statement, the Applicant makes no representation that the information cited in the Statement is, or is considered to be, in fact, prior art as defined by 35 U.S.C. §102.

Notwithstanding any statements by the Applicant, the Examiner is urged to form his own conclusion regarding the relevance of the cited information.

Serial No.: 10/644,267  
Conf. No.: 6263

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Art Unit: 1632

An early and favorable action is hereby requested.

Respectfully submitted,  
*Davis et al., Applicant*

By:



Helen C. Lockhart, Ph.D., Reg. No. 39,248  
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600 Atlantic Avenue  
Boston, Massachusetts 02210-2206  
Telephone: (617) 646-8000

Docket No.: C1040.70012US00  
Date: December 3, 2004  
**xNDDx**

08 06 2003

<b>FORM PTO-1449/A and B (Modified)</b>  <b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b>				APPLICATION NO.: 10/644,267		ATTY. DOCKET NO.: C1040.70012US00			
				FILING DATE: August 20, 2003		CONFIRMATION NO.: 6263			
				APPLICANT: Davis et al.					
				GROUP ART UNIT: 1632		EXAMINER: Not Yet Assigned			
Sheet	1	of	1						

U.S. PATENT DOCUMENTS

Examiner's Initials	Cite No.	U.S. Patent Document		Name of Patentee or Applicant of Cited Document	Date of Publication or of issue of Cited Document MM-DD-YYYY
		Number	Kind Code		
	A21	5,817,637		Weiner et al.	10-06-1998
	A22	5,830,876		Weiner et al.	11-03-1998

FOREIGN PATENT DOCUMENTS

Examiner's Initials	Cite No.	Foreign Patent Document			Name of Patentee or Applicant of Cited Document (not necessary)	Date of Publication of Cited Document MM-DD-YYYY	Translation (Y/N)
		Office/Country	Number	Kind Code			

OTHER ART — NON PATENT LITERATURE DOCUMENTS

Examiner's Initials	Cite No	Include name of the author (in CAPITAL LETTERS) title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, relevant page(s), volume-issue number(s), publisher, city and/or country where published.	Translation (Y/N)	
	C51	DAVIS et al., Chapter 18: DNA-based immunization. <i>in</i> Molecular and Cell Biology of Human Gene Therapeutics. George Dickson, ed., 1995: p368-87. (ISBN: 0 412 62550 4)		
	C52	HAHM et al., Efficacy of polyadenylic.polyuridylic acid in the treatment of chronic active hepatitis B. <i>Int J Immunopharmacol.</i> 1994 Mar;16(3):217-25.		
	C53	LIU et al., Immunization of non-human primates with DNA vaccines. <i>Vaccine.</i> 1997 Jun;15(8):909-12.		
	C54	MICHEL et al., DNA-mediated immunization to the hepatitis B surface antigen in mice: aspects of the humoral response mimic hepatitis B viral infection in humans. <i>Proc Natl Acad Sci U S A.</i> 1995 Jun 6;92(12):5307-11.		
	C55	STAATS et al., Mucosal immunity to infection with implications for vaccine development. <i>Curr Opin Immunol.</i> 1994 Aug;6(4):572-83. Review.		

EXAMINER:	DATE CONSIDERED:
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#EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to Applicant.

\*a copy of this reference is not provided as it was previously cited by or submitted to the office in a prior application, Serial No. \_\_, filed \_\_, and relied upon for an earlier filing date under 35 U.S.C. 120 (continuation, continuation-in-part, and divisional applications).

[NOTE - The Office hereby waives the requirement under 37 CFR 1.98 (a)(2)(i) for submitting a copy of each cited U.S. patent and each U.S. patent application publication for all U.S. national patent applications filed after June 30, 2003 and for all international applications that have entered the national stage under 35 USC 371 after June 30, 2003. See 37 CFR 1.491(b). For all patent applications filed on or before June 30, 2003, copies of cited U.S. patents and patent application publications are still required unless an eIDS is filed. Copies of all other patent(s), publication(s), or other information listed must still be provided, even if it was previously submitted to, or cited by, the U.S. Patent Office in an earlier application, unless the earlier application is identified by the IDS and is relied upon for an earlier filing date under 35 U.S.C. §120, and the copy was provided in the earlier application.]